EXHIBIT D

United States Patent [19]

Sams

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[45] **Date of Patent: Jun. 26, 1990**

[54] **CARTRIDGE-HOLDER ASSEMBLY FOR MEDICATION DISPENSING UNIT**

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[73] Assignee: **Hypoguard (UK) Limited**, Woodbridge, England

[21] Appl. No.: **237,147**

[22] Filed: **Aug. 26, 1988**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 205,198, Jun. 10, 1988, Pat. No. 4,865,591, which is a continuation-in-part of Ser. No. 81,241, Aug. 4, 1987, abandoned.

[51] **Int. Cl.**[5] **A61M 5/24**

[52] **U.S. Cl.** **604/232**; 604/208; 604/209; 604/220; 222/391

[58] **Field of Search** 604/68, 72, 208–210, 604/218, 220, 232, 234, 197; 222/325, 340, 391

[56] **References Cited**

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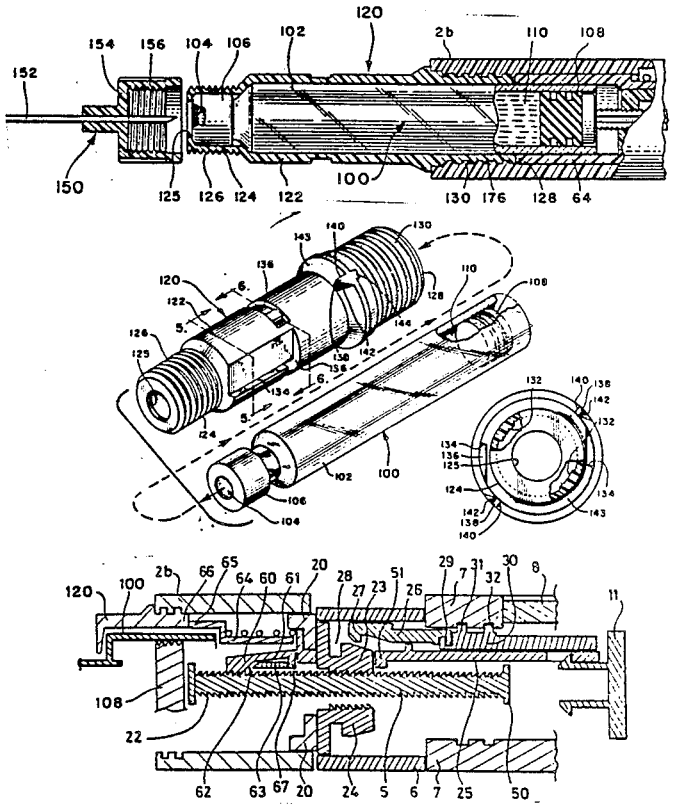
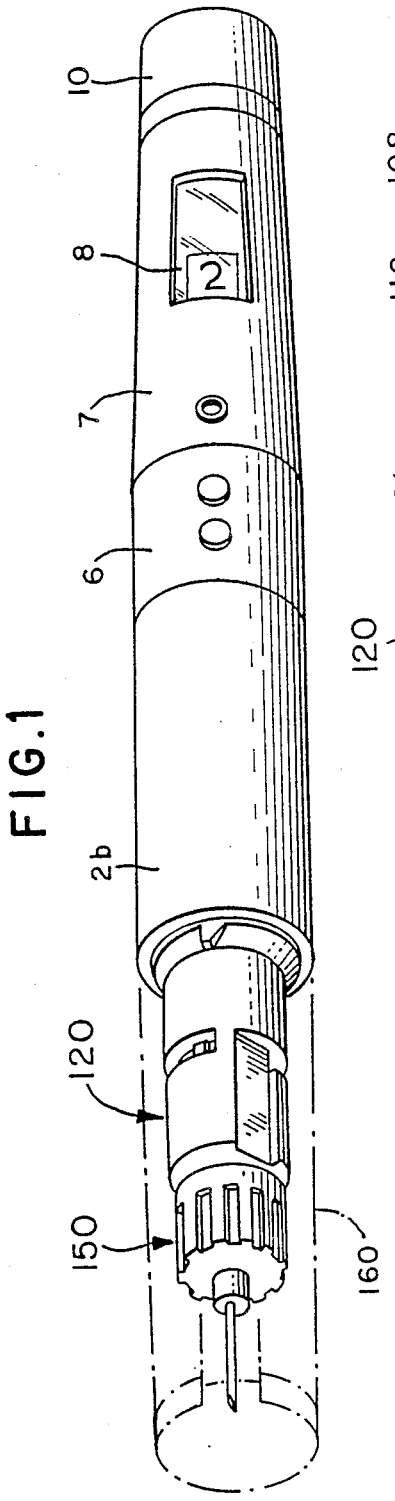
Attorney, Agent, or Firm—Willian Brinks Olds Hofer Gilson & Lione

[57] **ABSTRACT**

A cartridge assembly for a syringe-type medication dispensing unit includes a cartridge having a cartridge body with first and second ends. A pierceable membrane is mounted at the first end and a piston is mounted at the second end, with a volume of medication contained in the cartridge body between the membrane and the piston. A cartridge holder receives the cartridge and defines first and second ends. The first holder end defines a central opening and an external thread for mounting a double-ended needle. The second holder end defines an external thread for securing the holder to a medication dispensing unit and an actuating shoulder. The holder frictionally engages the cartridge to form an assembly which can be handled as a single modular unit with the cartridge held securely in the holder by frictional engagement.

23 Claims, 6 Drawing Sheets




10
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2b
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FIG. 1

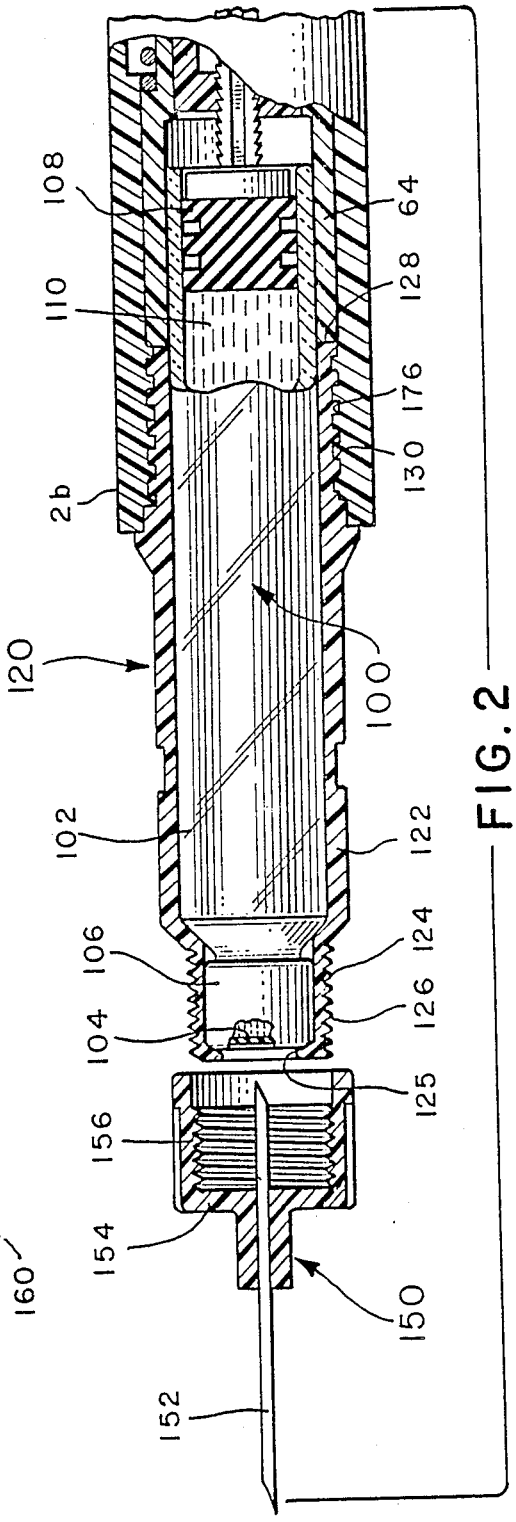
108
110
64
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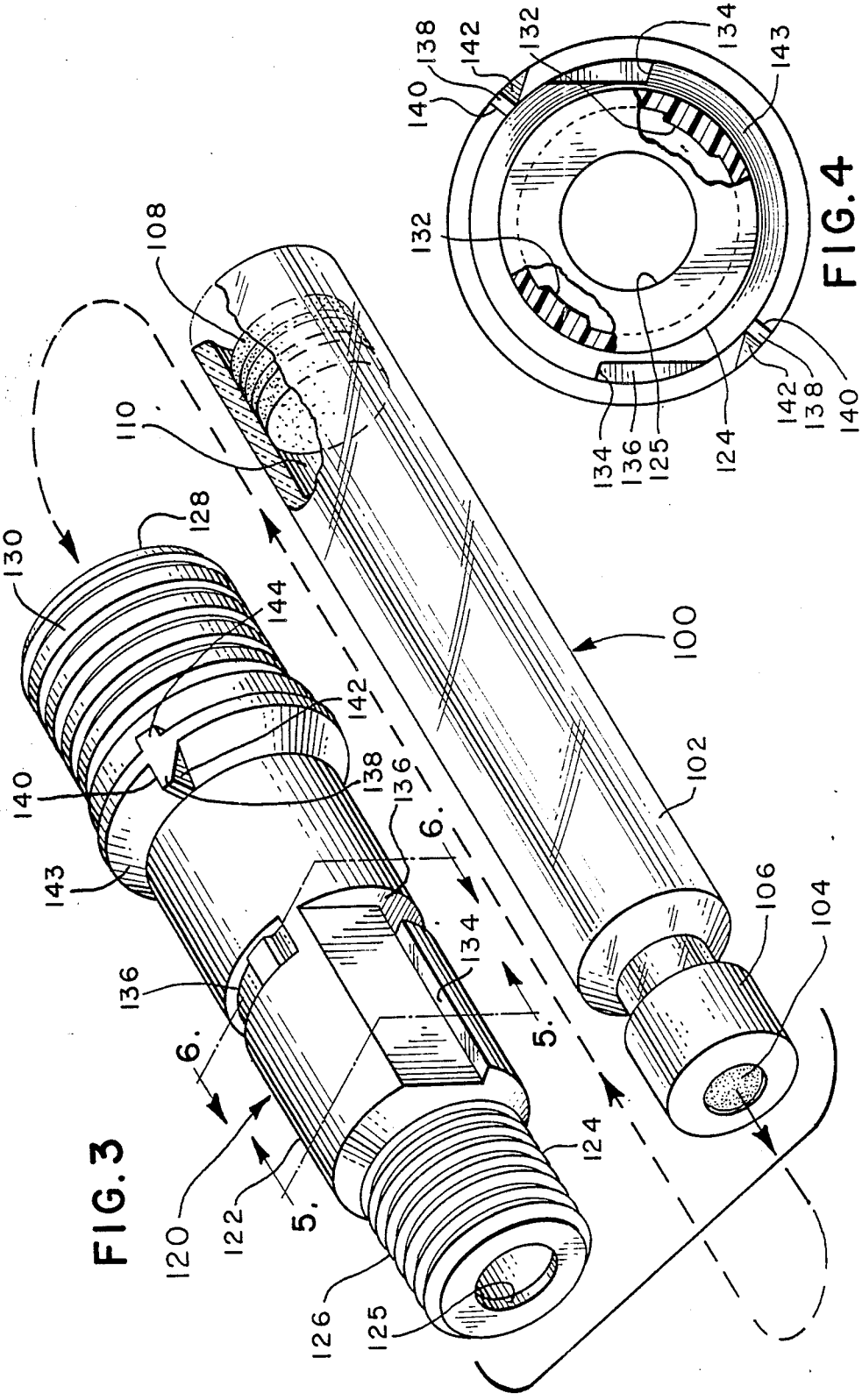
FIG. 2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6.
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FIG. 3

138
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125
124
142
138
140

FIG. 4

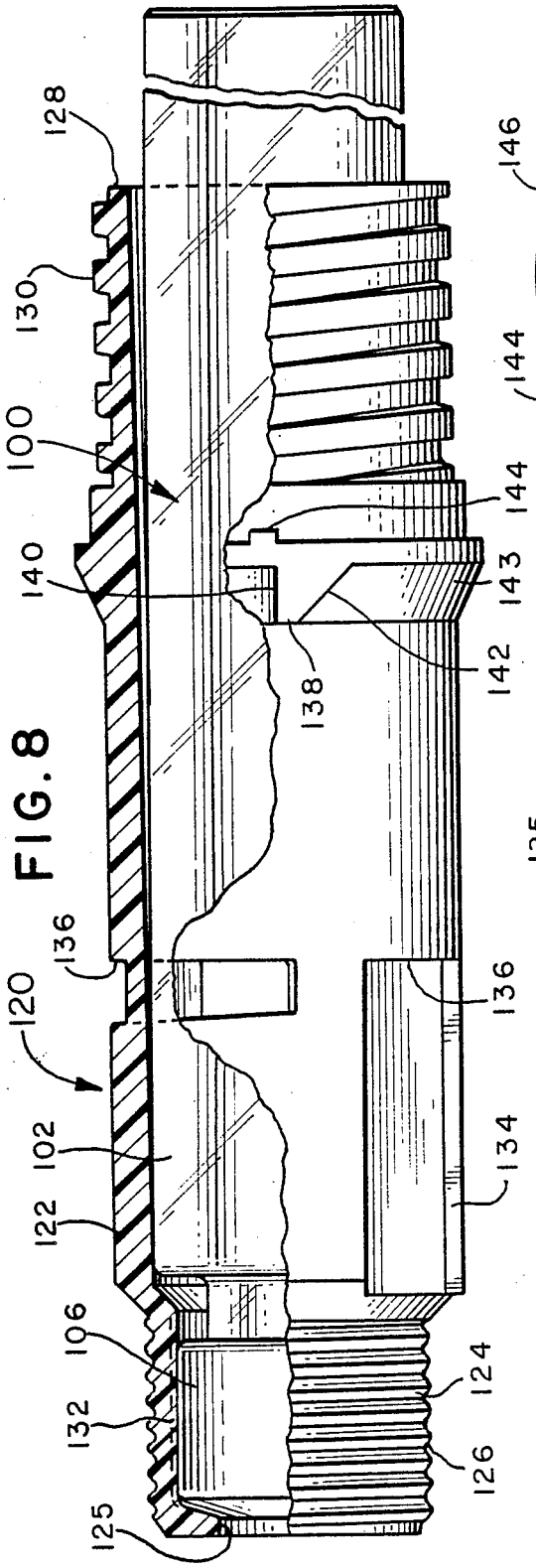


FIG. 8

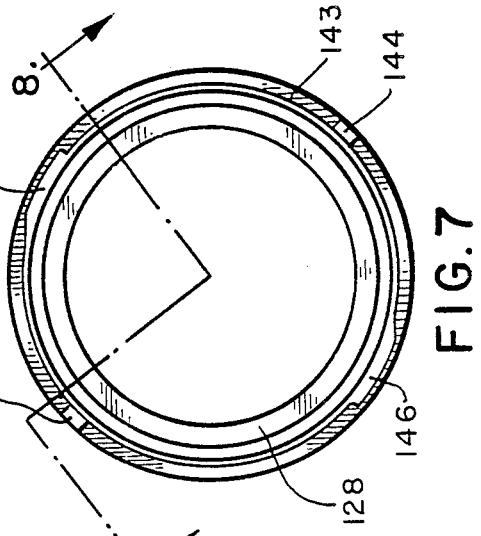


FIG. 7

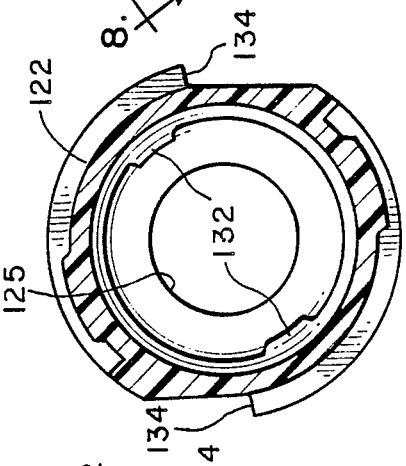


FIG. 6

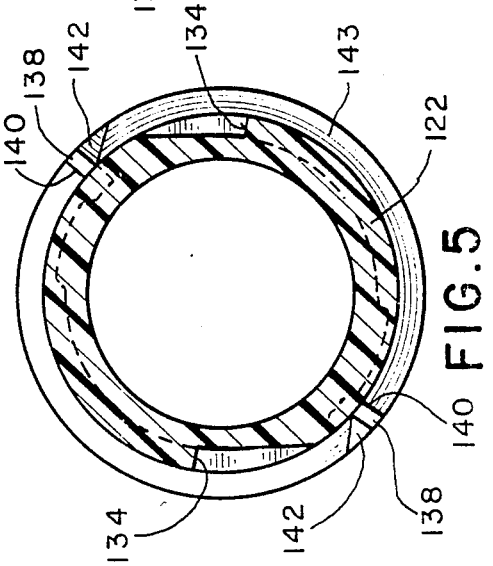


FIG. 5

FIG.9

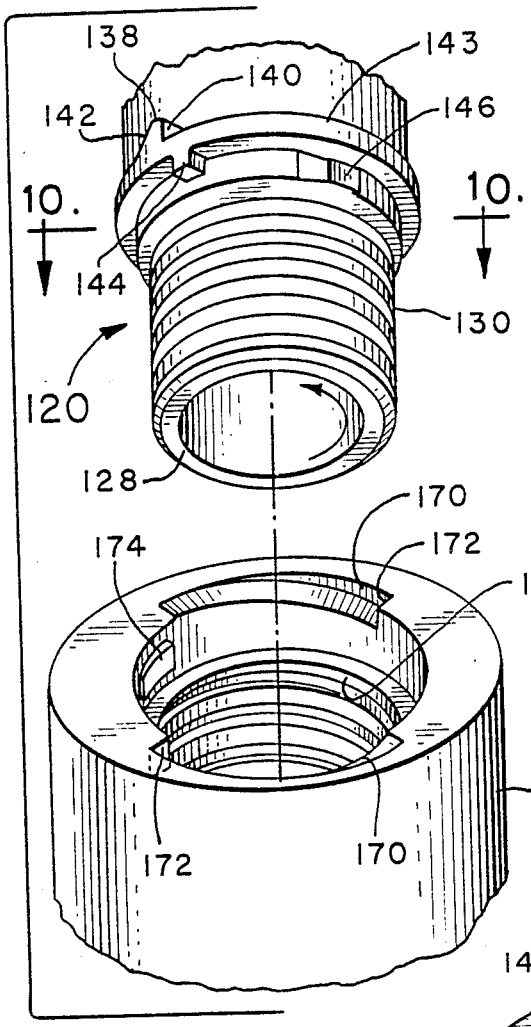
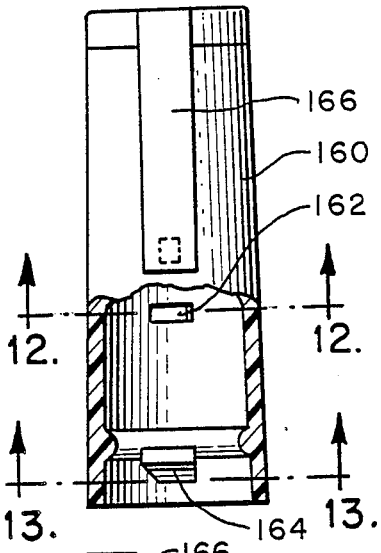


FIG.11



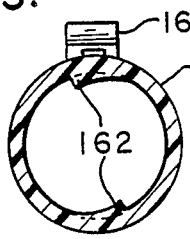


FIG.12

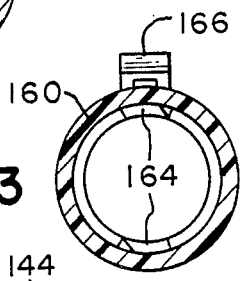


FIG.13

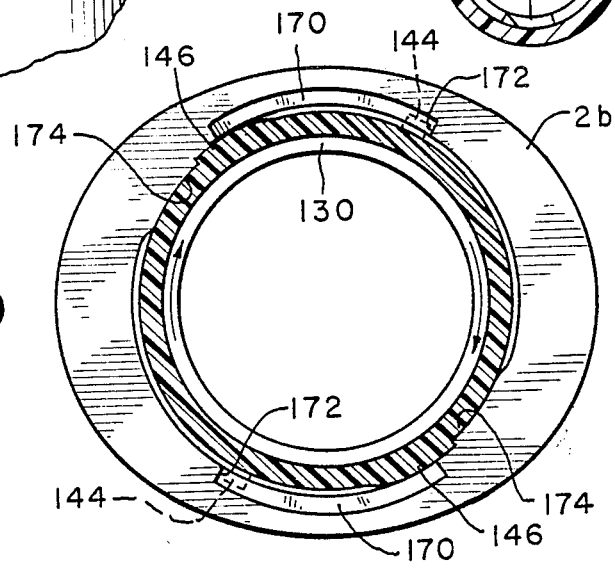
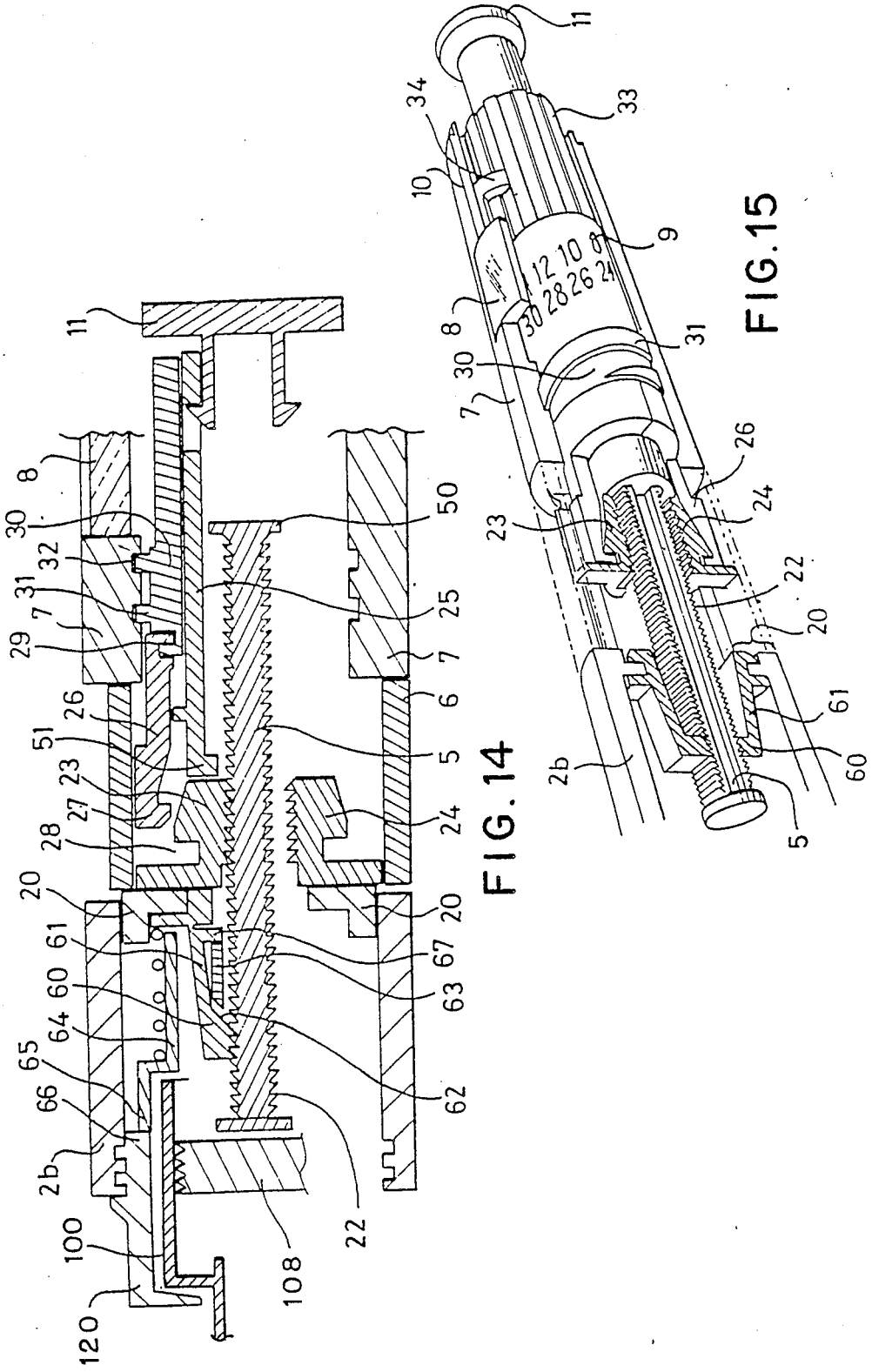


FIG.10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61
60
64
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66
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100
120
108
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67
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62

FIG. 15

FIG. 14

CARTRIDGE-HOLDER ASSEMBLY FOR MEDICATION DISPENSING UNIT

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of copending U.S. patent application Ser. No. 07/205,198, filed Jun. 10, 1988, now U.S. Pat. No. 4,865,591, which is in turn a continuation-in-part of U.S. patent application Ser. No. 07/081,241, filed Aug. 4, 1987, now abandoned. The entire text of these applications Ser. Nos. 07/205.198 and 07/081,241 is hereby incorporated by reference.

BACKGROUND OF THE INVENTION

The present invention relates to a cartridgeholder assembly for a measured dose medication dispensing device.

Patients suffering from diabetes often have to inject themselves with frequent doses of insulin and this can be done using a conventional syringe. However, such patients often also suffer from side effects of their illness and are not capable of accurately controlling the operation of such a syringe. It is therefore desirable that they should be provided with means for automatically administering an accurately controlled dosage. The dosage required by different patients can vary over quite wide ranges, from for example 2 units of insulin per dose to 30 or more units, and it is necessary to ensure that any device is capable of selecting a range of dosages simply and accurately.

Dispensing devices such as that shown in Rex U.S. Pat. No. 4,592,745 utilize a cartridge having a pierceable membrane at one end and a movable piston at the other, with a volume of a medication such as an insulin solution contained therebetween. The cartridge is mounted in a dispensing device which includes a plunger, a one-way mechanism that permits the plunger only to advance, and a mechanism for advancing the plunger to dispense medication.

The device disclosed in the Rex patent utilizes the rear rim of the cartridge to actuate the one-way mechanism: when the cartridge is removed the one-way mechanism releases, allowing the plunger to retract, but when the dispensing device is assembled with the cartridge in place the rear rim of the cartridge causes the one-way mechanism to engage the plunger. The cartridge is received loosely in a section of the device, and the one-way mechanism engaging apparatus resiliently holds the cartridge in position.

The dispensing device of the Rex patent has been proven effective and reliable in use. Nonetheless, it suffers from certain disadvantages related to the fact that the walls of the cartridge are formed of glass and in commercially practical cartridges it is difficult to control the overall length of the cartridge accurately. Resulting variations in the length of the cartridge cause the one-way mechanism to be engaged at a variable position as the cartridge enclosing section is screwed into place in the dispensing unit. If the cartridge is unusually long, the one-way mechanism will be engaged well before the cartridge enclosing section reaches its final position, and the plunger will then pressurize the contents of the cartridge as the section is screwed home. Such pressurization will produce a squirt of medication when the needle pierces the membrane. Some users may object to this unintended release of medication.

The variable length of the cartridge also imposes design constraints on the Rex dispensing device. As mentioned above, the cartridge fits loosely within the cartridge receiving section, and the cartridge is held in position by forces applied to the rear rim of the cartridge by the engaging apparatus for the one-way mechanism discussed above. This engaging apparatus must provide resilient support to the rim over the full range of cartridge lengths. Otherwise, the cartridge may be subjected to excessive axial forces, or it may alternately be left free to move axially in the dispensing device. The resilient mounting of the engaging apparatus in no way overcomes the problems discussed above related to unintended pressurization of the cartridge.

The present invention is directed to an improved cartridge-holder assembly that overcomes these prior art problems.

SUMMARY OF THE INVENTION

According to this invention, a cartridgeholder assembly is provided for a syringe-type medication dispensing unit. The cartridge comprises a cartridge body having first and second ends, a pierceable membrane mounted at the first end, and a piston mounted at the second end, with a volume of medication contained in the cartridge body between the membrane and the piston. The holder defines a first holder end which defines a central opening and means for mounting a double ended needle. The second holder end defines means for securing the holder to a medication dispensing unit and an actuating shoulder. The holder defines a central cavity shaped to receive and frictionally engage the cartridge to form an assembly that can be handled as a single, modular unit with the cartridge held frictionally in the holder.

This arrangement overcomes the prior art problems discussed above. The holder can easily be manufactured to high precision, and the actuating shoulder can therefore be accurately positioned to actuate the one-way mechanism just as the holder reaches its fully assembled position on the dispensing device. This substantially eliminates the problem of unintended pressurization of the cartridge before the needle is inserted into the membrane. Secondly, the releasable engagement between the cartridge and the holder allows the cartridge to be held in place without engagement of the rim. This relaxes design constraints on the engaging apparatus for the one-way mechanism.

As yet another advantage, the modular assembly of the holder and cartridge can be handled and assembled onto the dispensing device as a unit. This simplifies assembly by the patient.

The housing is preferably formed from a clear plastic material, and a user can therefore readily observe the movement of the piston within the cartridge and can assess the amount of medication in the cartridge. The housing also provides a measure of protection to the cartridge, both physical and against pathogenic organisms and other possible contamination.

The needle end of the cartridge can project through a terminal aperture in the housing or that end of the housing can be closed and can carry a needle or other outlet integrally therewith which projects axially inwardly into the housing to penetrate the membrane at the end of the cartridge.

The cartridge houses the piston which is to be moved by the plunger of the dispensing device. This piston can

be of conventional design and will usually form part of the cartridge as commercially available. The plunger acts on the piston and the piston can carry a socket or other recess to receive and locate the head of the plunger. In some cases, the plunger can be affixed to the piston and will form part of the cartridge as supplied, in which case the plunger will extend into the device when the cartridge is mounted on the device. However, it is preferred that the plunger form part of the device rather than of the cartridge and, for convenience the invention will hereinafter be described with respect to this configuration.

The invention itself, together with further objects and attendant advantages, will best be understood by reference to the following detailed description. taken in conjunction with the accompanying drawings

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of a syringe-type medication dispensing unit which includes a preferred embodiment of the cartridge-holder assembly of this invention.

FIG. **2** is a partial view of portions of the unit of FIG. **1** in partial section.

FIG. **3** is an exploded perspective view of the cartridge-holder assembly of FIG. **1**.

FIG. **4** is a front view in partial cutaway of the holder of FIG. **3**.

FIG. **5** is a cross sectional view taken along line **5—5** of FIG. **3**.

FIG. **6** is a cross sectional view taken along line **6—6** of FIG. **3**.

FIG. **7** is a rear view of the holder of FIG. **3**.

FIG. **8** is a longitudinal sectional view taken along line **8—8** of FIG. **7** in partial elevation.

FIG. **9** is an exploded perspective view of portions of the dispensing device of FIG. **1**.

FIG. **10** is a sectional view taken along line **10—10** of FIG. **9**.

FIG. **11** is an elevational view in partial cutaway of the cap of FIG. **1**.

FIG. **12** is a cross sectional view taken along line **12—12** of FIG. **11**.

FIG. **13** is a cross sectional view taken along line **13—13** of FIG. **11**.

FIG. **14** is a schematic cross sectional view of portions of the dispensing device of FIG. **1**.

FIG. **15** is a perspective view in partial cutaway of portions of the dispensing device of FIG. **1**.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS

FIGS. **1–10** show various views of the preferred embodiment of the cartridge-holder assembly of this invention, and FIGS. **11–15** provide further details relating to a preferred dispensing unit suitable for use with the cartridge-holder assembly of FIGS. **1–10**.

Turning now to FIGS. **1–10**, the preferred embodiment of the assembly of this invention comprises a cartridge **100** and a cartridge holder **120**. FIG. **1** shows the holder **120** mounted to a dispensing device, and FIG. **2** shows the cartridge **100** mounted within the holder **120**. As best shown in FIGS. **2** and **3**, the cartridge **100** includes a generally cylindrical body **102** which is closed at one end by a pierceable membrane **104** and is sealed at the other end by a movable piston **108**. A medication such as an insulin solution **110** is contained within the body **102** between the membrane **104** and the piston **108**. In the conventional manner, a collar **106** of metal surrounds the membrane **104** and secures the membrane **104** to the body **102** in a fluid-tight manner.

The cartridge **100** can be quite similar to conventional glass cartridges. Of course, the dimensions of the cartridge should be chosen to match the dispensing device. Preferably, the body **102** is glass coated with silicone to reduce friction with the piston. The piston **108** is preferably about two-thirds the axial length of conventional pistons, also to reduce friction.

As best shown in FIGS. **2** and **8**, the cartridge holder **120** comprises a tubular element **122** which defines a narrowed neck **124** which terminates in a central opening **125**. External threads **126** are formed around the exterior of the neck **124**. The opposite end of the cartridge holder **120** defines an annular actuating shoulder **128** positioned adjacent to a second set of external threads **130**. The tubular element **122** is sized to receive the cartridge **100** and defines in this embodiment two axially oriented raised lands **132** which are positioned to frictionally engage the collar **106** of the cartridge **100**.

The exterior of the tubular element **122** defines a number of features which cooperate with other components of the dispensing device described below. In particular, the tubular element **122** defines a pair of axial grooves **134** which communicate with respective circumferential grooves **136** to form L-shaped grooves that form part of a bayonet mount as described below. The tubular element **122** also defines a pair of stop members **138** which cooperate with a cap as described below. Each of the stop members **138** defines a transverse face **140** and an opposed sloping face **142**. The tubular element **122** also defines an annular flange **143** which in turn defines two rearwardly extending stop members **144**. A pair of ramps **146** are defined on the exterior of the tubular member **122** near the external threads **130**.

Preferably, the cartridge holder **120** is formed of a transparent plastic material such as polycarbonate. This construction allows a user to see the cartridge **100** within the cartridge holder **120** to check the correct insulin and to gauge the amount of medication **110** left in the cartridge **100**.

The minimum diameter of the inside of the tubular element **122** is greater than the maximum diameter of the cartridge **100**. For this reason, the tubular element **122** receives the cartridge **100** in an easy sliding fit such that the weight of the cartridge **100** will move the cartridge **100** in the tube **122** until the collar **106** contacts the raised lands **132**. A slight additional force will push the cartridge **100** to the fully seated position shown in FIG. **8**. In this position friction between the lands **132** and the collar **106** will prevent the cartridge **100** from falling out of the holder **120**. This arrangement facilitates assembly of the cartridge **100** into the holder **120**, because no frictional retarding force is encountered until the cartridge **100** is almost in the fully assembled position. There is therefore, less chance that a user will fail to push the cartridge **100** fully into the holder **120**. Furthermore because the cartridge **100** is engaged at the collar **106**, it is the diameter of the collar **106** rather than the diameter of the tube **122** that determines the tightness of the friction fit. In many cases, the diameter of the collar **106** can be controlled more closely than the diameter of the glass tube **122**, and in these cases this arrangement provides the further advantage of a more consistent fit.

Thus, the lands **132** frictionally engage the collar **106** to releaseably hold the cartridge **100** in the holder **120**

and thereby to form a modular unit which can be handled and assembled as a single device. As apparent in FIGS. **2** and **8**, the end of the cartridge **100** that mounts the piston **108** extends out of the cartridge holder **120** for a considerable distance. In this embodiment, that distance is greater than one-half inch. This allows the user to grasp the cartridge **100** when it is necessary to remove the cartridge **100** from the cartridge holder **120** for replacement.

As shown in FIG. **2**, the external threads **126** are sized to mate with internal threads **156** defined by a needle assembly **150**. This needle assembly **150** includes a double-ended hypodermic needle **152** which is mounted to a hub **154** that in turn defines the internal threads **156**. By threading the needle assembly **150** onto the external threads **126** the needle **152** is passed through the central opening **125** and the membrane **104**, into contact with the medication **110**.

As shown in FIGS. **1** and **11–13** the dispensing device includes a removable cap **160** which, when mounted in position, surrounds and protects the needle assembly **150** (if mounted), the cartridge holder **120**, and the cartridge **100**. This cap **160** defines a pair of internal lugs **162** sized to fit within the grooves **134**, **136** to form a bayonet mount in order to hold the cap **160** securely in position on the cartridge holder **120**. In addition, the cap **160** defines a pair of protruding elements **164** positioned to interact with the stop members **138**. When the cap **160** is rotated in a first locking direction, the protruding elements **164** engage the transverse faces **140**, thereby defining a stop position. This allows the cap **160** to be used as a tool to apply torque to screw the cartridge holder **120** into place on the dispensing device without overtightening the bayonet mount. When the cap **160** is rotated in a second unlocking direction, the protruding elements engage the sloping faces **140** to shift the cap **160** axially. The cap **160** can if desired define a clip **166** to retain the dispensing device in a pocket of the user.

As shown in FIGS. **2** and **9** the cartridge holder **120** mounts in the dispensing device by screwing the external threads **130** into a collar **2***b* defined by the dispensing device. This collar **2***b* defines internal threads **176** which mate with the external threads **130**. In addition the collar **2***b* defines elements which cooperate with the stop members **144** and the ramps **146** to define the fully assembled position of the cartridge holder **120** and to hold it in that position. In particular, the collar **2***b* defines a pair of spiral grooves **170**, each of which terminates in a transverse face **172**. When the cartridge holder **120** is threaded into the collar **2***b* the stop members **144** enter the spiral grooves **170**. The faces **172** prevent overtightening of the cartridge holder **120** in the collar **2***b*. The collar **2***b* defines ramps **174** which cooperate with the ramps **146** to define a detent that tends to hold the cartridge holder **120** in the fully assembled position (FIG. **10**).

As best shown in FIG. **2**, when the cartridge holder **120** is assembled in the collar **2***b* the rear end of the cartridge **100** is unrestrained. This arrangement provides particular advantages, because the overall length of the cartridge **100** is difficult to control with conventional manufacturing processes, as explained above. This embodiment accommodates varying lengths of the cartridge **100** because the rear rim of the cartridge body **102** does not contact the dispensing unit. In order to prevent the cartridge **100** from moving undesirably after the cartridge holder **120** has been threaded into the collar **2***b*, the cartridge **100** is restrained from movement by the frictional fit with the raised lands **132** described above.

As described in greater detail below, the dispensing device includes a plunger **5** that is advanced against the piston **108** to dispense the medication **110** through the needle **152**.

The movement of this plunger **5** is controlled in part by a one-way mechanism that allows the plunger **5** to advance but not to retract as long as the cartridge holder **120** is mounted to the collar **2***b*. However, when the cartridge holder **120** is removed from the collar **2***b* to replace the cartridge **100**, this one-way mechanism is released, to allow the plunger **5** to be retracted into the dispensing unit. The details of operation of this one-way mechanism and the manner in which this mechanism is released are explained in detail below in conjunction with FIGS. **14** and **15**. Here, it is enough to note that the one-way mechanism is controlled by the axial position of a member **64** which is slidably mounted in the collar **2***b*. This member **64** abuts the actuating shoulder **128** of the cartridge holder **120** and is shifted rearwardly to engage the one-way mechanism with the plunger **5** when the cartridge holder **120** is mounted in place in the collar **2***b*.

It is the actuating shoulder **128** rather than any part of the cartridge **100** that determines the position of the one-way mechanism actuating member **64**. The cartridge holder **120** can readily be manufactured to high accuracy with conventional molding techniques, and for this reason the actuating shoulder **128** can be precisely positioned to ensure that the member **64** is depressed at the proper instant, just before the cartridge holder **120** is fully assembled into the collar **2***b*. This ensures that there is no substantial movement of the cartridge holder **120** or the cartridge **100** after the one-way mechanism is engaged. This prevents the plunger **5** from exerting undue forces on the piston **108** and minimizes the unintended discharge of medication **110** when the needle **152** pierces the membrane **104**.

Further details of the one-way mechanism, and the operation of the actuating member **64**, as well as the advancing mechanism for the plunger **5** will now be described in conjunction with FIGS. **14** and **15**.

As shown in highly schematic form in FIG. **14** and as discussed above, the cartridge **100** is housed in the housing **120** which is screw fit into the collar **2***b* extending axially from the front end of the dispensing unit.

The dispensing device is provided with a pawl type one-way mechanism which engages teeth on the plunger **5** so as to prevent rearward movement of the plunger **5** once the housing **120** is in place. This one-way mechanism is shown at **60** in FIGS. **14** and **15** and is biassed to retract radially when the cartridge housing **120** is removed. For example, the housing can incorporate a twist mechanism which both locks the cartridge housing in position and actuates the one-way mechanism; or the shoulder **128** of the cartridge housing **120** can bear against part of the one-way mechanism as it seats home to actuate the one-way mechanism. The one-way mechanism disengages when the cartridge housing **120** is removed to allow the plunger **5** to be retracted into the device to permit a new cartridge **100** to be mounted on the dispensing device.

A preferred form of the one-way mechanism is shown in FIG. **14** and comprises a pair of diametrically opposed pawls **60** carried on spring arms **61** snap fitted onto an annular shoulder **20** to extend forward of the

shoulder into the axial socket in which the cartridge **100** is received. The pawls **60** have an inclined rearward face **62** which bears against a correspondingly angled face carried by a collet **63** mounted around the plunger shank and radially inward of arms **61**. The collet is attached to a spring loaded sleeve **64** which is a slideable fit within the socket and is spring biassed into its forward position. The front end of the sleeve **64** provides a stop **65** against which the shoulder **128** of the housing **120** bears as it is mounted in the device. This causes the sleeve **64** to be moved axially rearwardly to carry the inclined face of collet **63** clear of the inclined face **62** of the pawl and to bring the rear edge of collet **63** into contact with a stop **67** carried on the radially inward face of arm **61**. This causes the arm **61** to flex radially inward and urge pawl **60** into engagement with the teeth on the plunger **5**. When the housing **120** is removed to fit a new cartridge **100**, this allows the sleeve **64** to move forward under the thrust of the spring so that collet **63** moves forward of release stop **67** and bears against the inclined face **62** to lift the pawl **60** clear of the teeth on the plunger **5**. The plunger **5** can now be retracted into the device to enable another cartridge **100** to be fitted. By using the rear of the accurately molded housing **120** to actuate the pawl mechanism **60–67**, rather than the rim of the cartridge **100**, variations in the size of the cartridge **100** can be accommodated.

Rearwardly of shoulder **20**, the body of the device houses the plunger drive mechanism, the means for engaging and disengaging the drive mechanism from the plunger, and the dosage selection means. In the form of the device shown, these take the form of a series of members concentrically journalled around the plunger **5**.

As shown the housing comprises a rotatable section **6** which houses the drive engagement mechanism; a fixed section **7** containing the dosage selection mechanism and having a port **8** through which a scale **9** indicating the dose selected can be seen by the user; a further rotatable collar or sleeve **10** for operating the dosage selection mechanism: and a terminal axially operating push button **11** for driving the plunger **5** forward to dispense the selected dose. The various sections of the housing can have any desired external shape, but it is preferred that the housing **1**, sleeve **6** and section **7** have an oval external cross-section so that the relative rotational position of one with respect to the other can readily be detected by a user, notably by a blind person.

The plunger **5** preferably has a substantially circular cross-section but can have a squared, triangular or other cross-section shape if desired. For example, as shown in FIG. **15**, it may have two opposed flats along its length to guide the drive means.

The plunger **5** carries a series of circumferential ribs or teeth **22** which form an axial ratchet into which the one-way mechanism **21** and the radially clampable drive mechanism described below engage. The teeth **22** are of a saw tooth form with a scarp face of the teeth directed rearwardly. Preferably, the teeth extend axially for the full length of the plunger **5**. It is preferred that the axial distance from one tooth to the next corresponds to a dosage unit for the material being dispensed.

Located to the rear of shoulder **20** is the drive mechanism and the mechanism for engaging and disengaging this from the plunger. The drive mechanism is a pawl type mechanism which is radially engageable and disengageable with the teeth on the plunger and comprises two jaws **23** and **24** diametrically opposed to one another and carrying on their radially inward faces teeth which correspond to and engage with the teeth **22** on the plunger.

The jaws are normally urged radially outwardly, as shown for jaw **24** in FIG. **14**, by transverse coil springs acting between the jaws **23** and **24** or by other bias means (not shown) so that their teeth do not engage those of the plunger which is then free to move axially with respect to the jaws when they are in their outward position, but is locked to the jaws when they are in their radially inward position, as shown for jaw **23** in FIG. **14**.

The jaws are moved radially inward against the thrust of the coil springs by a pair of cams carried on the internal face of the rotatable section **6** of the housing or formed by the narrower diameter sectors of the oval cross-section of the rotatable section **6**. The user has to twist section **6** to engage or disengage the jaws from plunger **5** and thus engage or disengage the drive to the plunger. If desired, section **6** can be spring biassed towards the drive disengaging position so that the user always has to twist section **6** before the device can be used.

The shoulder **20**, as shown in FIG. **14**, defines the forward limit of the travel of the drive mechanism and provides the datum point from which the dosage is determined. In the device shown in FIGS. **14** and **15** the forward faces of jaws **23** and **24** butt against the rear face of shoulder **20** to set the zero or datum point for the dosage selection mechanism.

A push sleeve **25** journalled on plunger **5** and within the dosage selection mechanism described below acts axially on the rear faces of the jaws **23** and **24** when in their drive engaged position to drive the jaws and hence the plunger **5** forward. When the jaws are in the drive disengaged position, they still bear against the push sleeve so that they carry it axially rearwards with them during the dosage selection. The push sleeve **25** provides the mechanical link between the terminal push button **11** which a user presses and the jaws **23** and **24**.

The jaws **23** and **24** are moved axially by means of a split jaw drive sleeve **26** which has forward hooks **27** which engage similar recesses **28** at the rear of the jaws and rearward hooks **29** or other flexible linkages which connect the sleeve **26** axially to the forward end of the screw sleeve **30** of the dosage selection mechanism. When the jaws are in the drive disengaged position as shown for jaw **24** in FIG. **14** the hooks **27** and recesses **28** are engaged and the jaws can be moved axially with the screw sleeve **30**. When the jaws are in the drive engaged position, as shown for jaw **23** in FIG. **14**, the hooks **27** are released from recesses **28** to permit the jaws to move axially with sleeve **25** and free from the screw sleeve **30**.

The dosage selection mechanism is housed within section **7** of the housing and comprises a screw sleeve **30** journalled for rotation and axial movement upon push sleeve **25**. Sleeve **30** carries an external screw thread **31** which engages a similar thread **32** carried internally by section **7** of the body of the device. Sleeve **30** is rotated and thus caused to move axially by means of a collar driving the sleeve through a spined drive **33** shown in FIG. **15**. The window insert in port **8** preferably has a ratchet or clicker mechanism **34** to give an audible indication as the dose is selected.

Retraction of sleeve **30** carries the jaw drive sleeve **26** and the jaws **23** and **24** with it when they are in the

disengaged position and the dose selected can be seen through port **8**. Re-engagement of jaws **23** and **24** with the plunger breaks the latch **27/28** and allows the push sleeve **25** and the jaws **23** and **24** to move independently of the screw sleeve **30** and the jaw drive sleeve **26**.

To indicate when there is insufficient fluid left in the cartridge to achieve the next dose, a radial shoulder or stop **50** is located at or adjacent the rearward end of plunger **5**. This co-operates with a corresponding stop or shoulder **51** at the forward end of the push sleeve **25**. The stops engage when the push sleeve is retracted to the maximum extent possible as the plunger **5** approaches the extreme of its forward travel. The user can then see from the dose displayed at the port **8** whether the cartridge contains the requisite amount of fluid. Since the plunger drive is not engaged at this time, the user can then set the dosage mechanism to the required dose if this is less than the amount indicated as remaining in the cartridge without having to discharge fluid as with a conventional device.

Push sleeve **25** is provided with a push button end cap **11** protruding axially from the body of the device which the user depresses to drive the sleeve **25** forward within the housing until the front face of jaws **23** and **24** butt against the rear of shoulder **20**. The jaws **23** and **24** can only be moved rearwardly when they have been disengaged from the teeth **22** on the plunger **5**, since the one-way mechanism will prevent rearward movement of the plunger **5**. If a user attempts to set the dosage mechanism while the drive is engaged, he will detect resistance to rotation of sleeve **10**. If he ignores this, the spline drive **33** between collar **10** and the screw sleeve **30** will be over-ridden to release the screw sleeve to prevent damage to the mechanism. However, unless the drive is engaged, depression of button **11** will not achieve any forward movement of the jaws or discharge of fluid from the cartridge **100**.

The above device can be manufactured in many suitable materials and readily lends itself to manufacture by injection molding of suitable plastics materials with the various components being snap fits upon one another.

In operation, a user initially prepares the dispensing device for use by removing the holder **120**, inserting a cartridge **100** in the holder **120**, and then screwing the holder **120** into place on the collar **2***b*. The needle assembly **150** is then screwed into place on the housing **120**. The user then rotates the sleeve **6** to disengage the drive mechanism if this has not already been done. Jaws **23** and **24** should be seated against the rear face of shoulder **20**, the zero setting, from the previous use of the device, but the screw sleeve **30** will be at the dosage position previously selected. The user can thus see what dose was last administered where a sequence of different doses has to be administered. Collar **10** is rotated, say clockwise, to bring sleeve **30** to its forward position at which the latching mechanism **27/28** engages the jaws **23** and **24** and seats them firmly against the rear face of stop **20**. The engagement of the latches can be used to provide an audible signal when this occurs, or the resistance to further forward movement will provide the signal to the user that the zero setting has been reached. The dosage displayed through port **8** will now read zero.

Collar **10** is then rotated counter-clockwise the desired number of turns, as evidenced by the number of clicks heard or by the dose displayed at the port **8**, to retract screw sleeve **30**, the jaw drive sleeve **26** and the jaws **23** and **24** and the push sleeve **25** the desired distance with respect to plunger **5**. This will also cause the push button **11** to be extended from the rear end of the device. If the user inadvertently turns the collar **10** too far, it can be rotated clockwise to the correct position without moving the plunger.

Sleeve **6** is then rotated to re-engage the positive drive between the push sleeve **25**, the jaws **23** and **24** and the plunger **5**. This action will also disengage the latch **27/28** between jaws **23** and **24** and the jaw drive sleeve **26**. At this point the device is cocked and ready to dispense the desired dose from the cartridge. However, the device has required a series of positive actions to achieve this state and would not normally be retained by a user in the cocked state, but would be stored with the drive disengaged so that accidental actuation of the device can not occur.

The user then inserts the point of needle **3** into his arm, buttock or other suitable point in his body and depresses button **11** to administer the dose of insulin. The dose is administered by depressing the button fully. If the button is not depressed fully, the user can detect this and can complete the dose administration. If desired, a colored band can be mounted around button **11** which will remain partially exposed until the button is fully depressed. Release of pressure on button **11** does not allow the plunger **5** to retract as with previous designs, so that jerky or interrupted depression of button **11** does not allow the user to pump the device to administer an excessive dose.

When the full dose has been administered, the jaws **23** and **24** will butt against the rear of shoulder **20**. Due to the action of the one-way mechanism **21**. **60–67**, the blocks **23** and **24** cannot be retracted and administration of a further dose of insulin is not possible until the whole process of dose selection and re-cocking of the device is carried out. The device will therefore resist accidental overdosing due to repeated pressing of button **11**.

As stated above, the cartridge-holder assembly of this invention finds use wherever it is desired to provide a removable cartridge for a measured dose syringe, for example in the administration of other medicaments or in dispensing accurately known amounts of a fluid, for example in blood tests or analytical work. It will also be appreciated that the assembly may be altered in ways which do not affect the fundamental operating concept of the assembly, for example by using other materials and configurations.

It is therefore intended that the foregoing detailed description be regarded as illustrative rather than limiting, and that it be understood that it is the following claims, including all equivalents, which are intended to define the scope of this invention.

I claim:

1. A cartridge assembly for a syringe-type medication dispensing unit, said assembly comprising:

a cartridge comprising a cartridge body having first and second ends, a pierceable membrane mounted at the first end, and a piston mounted at the second end, with a volume of mediation contained in the cartridge body between the membrane and the piston;

a cartridge holder having first and second ends, said first holder end defining a central opening and means for mounting a double ended needle, said second holder end defining means for securing the holder to a medication dispensing unit and an actuating shoulder, said holder defining a central cavity;

one of said central cavity and said cartridge being shaped with a plurality of raised lands adapted to frictionally to engage the opposed surface of the other of said cartridge and cavity so as to form an assembly which can be handled as a single modular unit with the cartridge held securely in the holder.

2. The invention of claim 1 wherein the double ended needle mounting means comprises a first set of external threads.

3. The invention of claim 1 wherein the holder securing means comprises a second set of external threads.

4. A cartridge assembly for a syringe-type medication dispensing unit, said assembly comprising:

a cartridge comprising a cartridge body having first and second ends, a pierceable membrane mounted at the first end, and a piston mounted at the second end, with a volume of medication contained in the cartridge body between the membrane and the piston;

a cartridge holder having first and second ends, said first holder end defining a central opening and means for mounting a double ended needle, said second holder end defining means for securing the holder to a medication dispensing unit and an actuating shoulder, said holder defining a central cavity shaped to receive and frictionally engage the cartridge to form an assembly which can be handled as a single, modular unit with the cartridge held securely in the holder;

wherein the holder securing means comprises a second set of external threads; and

wherein the modular unit is mounted to a syringe type medication dispensing unit having a plunger engageable with the piston, a one-way mechanism engaged with the plunger, and an actuating member for the one-way mechanism, wherein the second holder end is received within the dispensing unit, wherein the second set of external threads is engaged with the dispensing unit, and wherein the actuating shoulder is engaged with the actuating member.

5. The invention of claim 4 wherein the dispensing unit and the holder define a detent system which holds the second set of external threads in engagement with the dispensing unit.

6. The invention of claim 5 wherein the detent system comprises inter engaging ramps on the holder and the dispensing device adjacent the second set of external threads.

7. The invention of claim 1 wherein the modular unit is mounted to a cap which encloses the first end of the holder, wherein the holder defines at least one stop member wherein the cap defines at least one lug, wherein at least one of the stop member and lug has a transverse face and a sloping face oriented such that the stop member and lug abut at the transverse face to limit rotation of the cap when the cap is rotated in a first direction with respect to the holder, and the stop member and the lug abut at the sloping face to shift the cap axially along the holder when the cap is rotated in a second direction with respect to the holder.

8. The invention of claim 1 wherein the modular unit is mounted to a cap which encloses the first end of the holder; wherein one of the holder and the cap defines at least one groove having an axial portion and a circumferential portion; and wherein the other of the holder and the cap defines a protruding element shaped to slide in the groove to secure the cap and holder together in a bayonet mount.

9. The invention of claim 1 wherein the holder frictionally engages only the first end of the cartridge.

10. The invention of claim 9 wherein the cartridge defines an annular collar disposed around the membrane, and wherein the holder frictionally engages the cartridge only at the collar.

11. The invention of claim 10 wherein the plurality of raised lands are positioned on the holder to frictionally engage the collar.

12. The invention of claim 2 further comprising:

a needle assembly comprising a double ended needle secured to a mounting element which defines a set of internal threads engaged with the first set of external threads of the holder, with one end of the needle passing through the membrane and in contact with the medication.

13. The invention of claim 1 wherein the medication comprises an insulin solution.

14. The invention of claim 1 wherein the second end of the cartridge extends out of the holder by a distance of about ½ inch or more.

15. A cartridge assembly for a syringe-type medication dispensing unit, said assembly comprising:

a cartridge comprising a cartridge body having first and second ends, a pierceable membrane mounted at the first end, and a piston mounted at the second end, with a volume of medication contained in the cartridge body between the membrane and the piston and an annular collar disposed around the membrane;

a cartridge holder having first and second ends, said first holder end defining a central opening and a first set of external threads, said second holder end defining an actuating shoulder and a second set of external threads said holder defining a central cavity shaped to receive the cartridge with the pierceable membrane adjacent the central opening, said cartridge having a length greater than that of the holder such that the second end of the cartridge extends out of the holder,

said holder defining a plurality of raised lands positioned to frictionally engage the collar to form an assembly which can be handled as a single, modular unit with the cartridge held removably in the holder by friction between the collar and the holder, said holder shaped to receive the cartridge freely until the lands engage the collar, such that the weight of the cartridge will move the cartridge into the holder until the lands contact the collar.

16. The invention of claim 15 wherein the modular unit is mounted to a syringe type medication dispensing unit having a plunger engageable with the piston, a one-way mechanism engaged with the plunger, and a one-way mechanism actuating member, wherein the second hold end is received within the dispensing unit, wherein the second set of external threads is engaged with the dispensing unit, and wherein the actuating shoulder is engaged with the one-way mechanism actuating member.

17. The invention of claim 16 wherein the dispensing unit and the holder define a detent system which the second set of external threads in engagement with the dispensing unit.

18. The invention of claim 17 wherein the detent system comprises inter-engaging ramps on the holder

and the dispensing device adjacent the second set of external threads.

19. The invention of claim **18** wherein the modular unit is mounted to a cap which encloses the first end of the holder, wherein the holder defines at least one stop member, wherein the cap defines at least one lug, wherein at least one of the stop member and lug has a transverse face and a sloping face oriented such that the stop member and lug abut at the transverse face to limit rotation of the cap when the cap is rotated in a first direction with respect to the holder, and the stop member and the lug abut at the sloping face to shift the cap axially along the holder when the cap is rotated in a second direction with respect to the holder.

20. The invention of claim **15** wherein the modular unit is mounted to a cap which encloses the first end of the holder; wherein one of the holder and the cap defines at least one groove having an axial portion and a circumferential portion; and wherein the other of the holder and the cap defines a protruding element shaped to slide in the groove to secure the cap and holder together in a bayonet mount.

21. The invention of claim **15** further comprising:

a needle assembly comprising a double ended needle secured to amounting element which defines a set of internal threads engaged with the first set of external threades of the holder, with one end of the needle passing through the membrane and in contact with the medication.

22. The invention of claim **15** wherein the medication comprises insulin.

23. The invention of claim **15** wherein the lands are axially oriented.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 4,936,833
DATED : June 26, 1990
INVENTOR(S) : Bernard Sams

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

IN THE CLAIMS

Col. 10, line 59, claim 1, delete "mediation" and substitute therefor --medication--;

Col. 12, line 58, claim 16, delete "hold" and substitute therefor --holder--.

Col. 12, line 64, claim 17, after "which" insert --holds--.

Col. 14, line 8, claim 21, delete "amounting" and substitute therefor --a mounting--.

Col. 14, line 10, claim 21, delete "threades" and substitute therefor --threads--.

Signed and Sealed this

Twenty-second Day of December, 1992

Attest:

Attesting Officer

DOUGLAS B. COMER

Acting Commissioner of Patents and Trademarks